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DEPARTMENT OF ENERGY

Office of Environment, Safety and Health

Notice of Availability of Funds and Request for Applications To Support Medical Surveillance for Former Department of Energy Workers

AGENCY: Office of Environment, Safety and Health, DOE.

ACTION: Notice of availability of funds and request for applications.

SUMMARY: The Department of Energy (DOE) Office of Environment, Safety and Health (EH) announces the availability of additional funds to evaluate former workers whose employment at departmental facilities may have placed their long-term health at significant risk. This Notice of Availability of Funds and Request for Applications to Support Medical Surveillance for Former DOE Workers does not affect cooperative agreements awarded pursuant to a similar Federal Register announcement published on March 1, 1996. This new Notice is issued subsequent to the more general Continuation of Solicitation for Epidemiology and Other Health Studies Financial Assistance Program published in the Federal Register (61 FR 53903) on October 16, 1996.

DATES: Applications submitted in response to this announcement must be received by June 3, 1997.

ADDRESSES: U.S. Department of Energy, 19901 Germantown Road, Germantown, Maryland 20874-1290.

FOR FURTHER INFORMATION CONTACT: Requests for further information and application forms may be directed to Dr. John Peeters, Office of Occupational Medicine and Medical Surveillance (EH-61), Telephone: (301) 903-5902; facsimile: (301) 903-5072. Applications may be submitted to Dr. Peeters at the address listed above.

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SUPPLEMENTARY INFORMATION:

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I. Purpose

Section 3162 of the National Defense Authorization Act for Fiscal Year 1993 (Pub. L. 102-484) directs the Secretary of Energy, in consultation with the Secretary of Health and Human Services, to develop a program of medical evaluation for current and former DOE workers at significant risk for health problems due to exposures to hazardous or radioactive substances during employment.

On March 1, 1996, the first ``Notice of Availability of Funds and Request for Applications to Support Medical Surveillance for Former DOE Workers" was published in the Federal Register (61 FR 8047). In September 1996, six cooperative agreements were awarded to begin phase I projects at the following DOE sites: Hanford Site, Nevada Test Site, Rocky Flats Environmental Technology Site, Portsmouth Gaseous Diffusion Plant, Paducah Gaseous Diffusion Plant, and the Oak Ridge Reservation. At five of the sites, the project teams are focusing on a selected group or groups of former workers (e.g., production workers or construction workers). At the Rocky Flats Site, the project team is initially assessing all former workers.

This second Notice announces the availability of funds for up to three new projects to be funded through cooperative agreements. In particular, DOE is interested in applications that will help determine the potential need for medical surveillance for former workers at major DOE sites not included in the six phase I projects listed above. The new projects will identify, and, where appropriate, notify and medically screen groups of former workers who are potentially at significant risk for health problems due to work-related exposures.

Experience with all of these projects will help DOE to evaluate options for a possibly more comprehensive medical surveillance program for former workers and to determine how such a program may be integrated effectively with other ongoing site activities.

II. Project Description

DOE intends to award up to three cooperative agreements with specific goals identical to the goals of the six ongoing projects. The goals of the projects are to:

<bullet> Identify groups of workers at significant risk for occupational diseases.

<bullet> Notify members of these risk groups.

<bullet> Offer these workers medical screening that can lead to medical interventions.

Each cooperative agreement will begin with an award for the first year for a phase I needs assessment. Under the same cooperative agreement, the project potentially could continue into phase II medical screening, if determined by DOE to be warranted.

Pursuant to this Notice, there will be up to three cooperative agreements awarded, totalling about $1.5 million. The initial funding for each new cooperative agreement will be for a phase I needs assessment only. Phase I is expected to take approximately 12 months. Phase II, if warranted, will be funded through continuation awards under the same cooperative agreement. Phase II could continue up to 4 years, renewable annually. The award continuation for phase II, if made, will be based on the results from phase I, the availability of funds, and negotiation of the costs for phase II. Only those who participate in phase I will be eligible to participate in phase II.

Phase I

During phase I, the awardees will conduct a comprehensive needs assessment. The needs assessment will include a review of existing site-specific information and other means to initially identify the most significant radiation and nonradiation exposures. During phase I, investigators will conduct the following tasks:

1. Identify existing information relevant to exposure and health outcomes among former workers;
2. Utilize this information to identify or develop viable methods for contacting these former workers;
3. Provide an initial determination of the most significant worker hazards, problems and concerns for each site;
4. Identify approaches for conducting the project in partnership with unions, site management, operating contractors, community representatives, and State and local health officials; and
5. Attend semiannual DOE-coordinated meetings of investigators to share information on ongoing needs assessments.

During phase I, investigators will develop a detailed plan and proposed budget for phase II focusing on the groups of workers

determined to be at significant risk for adverse health effects during the needs assessment. The plan for phase II, and a draft of the needs assessment, is expected at least 60 days prior to the conclusion of phase I. Phase I will conclude with delivery of the final needs assessment to DOE.

Phase II

DOE will determine the need for phase II activities based upon the phase I results and, if appropriate, will support these efforts through continuation awards. Where phase II plans are approved by DOE, the investigators will conduct the following tasks:

1. Identify and locate those former workers who based on the results of the phase I needs assessment are at significant risk of adverse health effects;
2. Ascertain the health concerns of former workers identified in task 1 related to their past DOE employment;
3. Communicate risk information to former workers regarding the nature of their health risk and discuss the actions that could be taken;
4. Provide medical screening to targeted former worker populations based on exposure history and the availability of acceptable screening tests;
5. Assist in the coordination of referrals, diagnostic workup, and followup treatment, including the coordination with workman's compensation and other existing insurance and benefits programs;
6. Ensure dialogue with local parties concerned with the project;
7. Evaluate former workers satisfaction with the project; and
8. Attend semiannual DOE-coordinated meetings of investigators to share information on ongoing screening programs.

Potential Sites

A program policy factor for DOE is the determination of potential needs for medical surveillance for former workers at major DOE sites not included in the cooperative agreements awarded in September 1996.

Applicants for the cooperative agreements will propose individual (or alternative groups of) DOE sites for study and justify the technical factors used in site(s) selection. Such technical factors should include:

1. Presence of existing worker and community health programs;
2. Availability of information on former workers and their exposures;

3. Levels and types of exposures;
4. Number of former workers and access to them;
5. Concerns of workers about specific past exposures;
6. Concerns of DOE site managers and operating contractors about specific past exposures; and
7. Concerns of both national and local unions about past exposures.

III. DOE's Policy on Protection of Human Subjects Reviews

DOE has codified the Federal Policy for the Protection of Human Subjects in 10 CFR part 745. As defined in this regulation, human subjects research may include a broad range of studies. DOE has determined that both phase I and phase II of the former worker medical surveillance program fall under the broad definition of human subjects research, and, accordingly, each phase requires Institutional Review Board (IRB) review and approval. Phase I activities will involve the review and possible collection of identifiable private information, either through records review or personal interviews. Therefore, IRB reviews are necessary to ensure adequate protection of privacy. Phase II, involving medical surveillance of former workers, including the handling of personal medical records, requires IRB review to ensure that all necessary protections are implemented.

It is the DOE's policy that each study involving DOE workers must be reviewed by the ``local'' DOE site institutional review board. ``Local'' IRB reviews will take place following award of the new cooperative agreements, and annually thereafter. Applicants also may have to comply with their own institution's requirements regarding review of human subjects research. Documentation of all reviews must be submitted to DOE prior to implementation of each phase.

IV. Applications

This Notice of Availability is issued pursuant to DOE regulations contained in 10 CFR part 602: ``Epidemiology and Other Health Studies Financial Assistance Program'', as published in the Federal Register on January 31, 1995 (60 FR 5841). The Catalog of Federal Domestic Assistance number for 10 CFR part 602 is 81.108, and its solicitation control number is EOHSFAP 10 CFR part 602. 10 CFR part 602 contains the specific requirements for applications, evaluation, and selection criteria. Only those applications following these specific criteria and forms will be considered. Application forms may be obtained at the address cited above.

V. Proposal Format

The proposal shall contain two sections, technical and cost. Technical proposals shall be no more than fifty (50) pages in length; resumes of proposed key personnel should be submitted as an appendix to the technical proposal and will not be counted against the page limit. Cost proposals shall have no page limit. Because each project will be conducted in two phases, and the scope of phase II is dependent on the results of phase I, the technical description for phase II may be less specific than that for phase I, but must clearly demonstrate a capability to conduct phase II. It is left to the proposer to determine how best to structure the proposal. However, the following information shall be included:

a. Proposals shall include a detailed project description that discusses the specific tasks to be performed under the proposed project. At a minimum, the tasks listed under section II above (Project Description) must be described (in detail for phase I tasks and more generally for phase II tasks). The project description must include clear statements of what is not known and what is uncertain, as well as statements of what is known. The project description must describe how independent, external peer review of the results of the project will be conducted. The project description must demonstrate that the offeror has the ability to integrate its work with the activities of other organizations conducting medical surveillance activities.

b. Proposals must demonstrate the competency of research personnel and the adequacy of resources. Proposals must demonstrate that the offeror is perceived as neutral and credible, and is capable of conducting scientifically valid and responsible medical surveillance projects.

Proposals must demonstrate that the offeror has the experience and capability to plan, organize, manage, and facilitate worker and union participation in planning and execution. Proposals must also demonstrate that the offeror has the experience and ability to effectively communicate complicated scientific information on potential risks and uncertainties to workers, local and national stakeholders, concerned citizens, and decision makers at all levels. Proposals must demonstrate that the offeror presently has or is capable of obtaining staff with the training, expertise, and experience needed to conduct scientifically complex needs assessments and medical surveillance programs. Proposals must identify the technical and scientific staff that will actually conduct the studies and detail their professional experience, as well as their level of program involvement. Proposals must demonstrate that the offeror has capability, for both financial and scientific management, and a demonstrated skill in planning and scheduling projects of comparable magnitude to those proposed under this Notice.

c. The cost proposal for phase I must include a summary breakdown

of all costs, and provide a detailed breakdown of costs on a task-by-task basis for each task contained in the project description. Costs for phase II tasks may be more general estimates since the initial award will be for phase I only. Any expectation concerning cost sharing must be clearly stated. Cost sharing is encouraged, but it will not be considered in the selection process.

d. The cost proposal for phase I shall include an estimate of the costs of copying, filming, scanning, or abstracting data needed for the project, charges associated with site computer programming, and any additional support not routinely provided by DOE (see Section VII, DOE's Role). This amount should be included in the proposed budget for phase I.

VI. Application Evaluation and Selection

Applications will be subjected to formal merit review (peer review) and will be evaluated against the following criteria listed in descending order of importance and codified at 10 CFR 602.9(d):

1. Scientific and technical merit of the proposed research;
2. Appropriateness of the proposed method or approach;
3. Competency of research personnel and adequacy of proposed resources; and
4. Reasonableness and appropriateness of the proposed budget.

Applications will be peer reviewed by evaluators apart from DOE employees and contractors as described in the Office of Environment, Safety and Health's Merit Review System (57 FR 55524, November 25, 1992) and at 10 CFR 602.9(c). Submission of an application constitutes agreement that this is acceptable to the investigator(s) and the submitting institution.

In accordance with 10 CFR 602.9(e), DOE shall also consider, as part of its evaluation, program policy factors such as an appropriate balance among sites for efforts to target former workers potentially in need of medical surveillance. As noted above in section

II (Project Description, Potential Sites), a program policy factor for DOE is the determination of potential needs for medical surveillance for former workers at major DOE sites not included in the cooperative agreements awarded in September 1996.

VII. DOE's Role

In order for DOE to utilize cooperative agreements for these medical surveillance projects, there must be substantial involvement

between DOE and any awardee(s). DOE established the core tasks for these projects and prepared this Federal Register Notice of Availability. DOE will conduct the selection and award process, which will include evaluations by persons outside the Federal government. DOE will evaluate the results of phase I and, where warranted, authorize and fund phase II. DOE will facilitate awardee access to the target sites and help familiarize investigators with the facility and historical operations. DOE will facilitate access to exposure records, including the identification and retrieval of records relating to DOE activities, and declassification of records, as needed. DOE will establish requirements for data collection and handling. DOE will consult with project investigators and coordinate semiannual meetings. DOE will interact with an independent advisory group that will provide advice to DOE and to project investigators. Finally, DOE will monitor and evaluate the results of the projects, including the participant's level of satisfaction, to determine how these projects could be expanded to other groups of former workers both at the project sites and at other DOE sites. In addition to helping former workers, information gained from these projects will contribute to DOE's ongoing efforts to improve health and safety programs for current workers.

VIII. Applicants

Applicants for the cooperative agreements could include domestic nonprofit and for profit organizations, universities, medical centers, research institutions, other public and private organizations, including State and local governments, labor unions and other employee representative groups, and small, minority and/or women-owned businesses. Consortiums of interested organizations are encouraged to apply. Awardees for each project will work cooperatively with former workers, DOE site officials, DOE operating contractors, labor organizations, health officials, and designated community representatives.

Issued in Washington, D.C., on March 14, 1997.
Paul J. Seligman,
Deputy Assistant Secretary for Health Studies.
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